NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS DEUTSCHLAND GMBH, AVENTIS PHARMA S.A., ABBOTT GMBH & CO. KG and ABBOTT LABORATORIES Plaintiff, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD, Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-CV-5855 (DMC-JAD)

DENNIS M. CAVANAUGH, U.S.D.J.

This matter comes before the Court upon five motions in limine filed by Sanofi Aventis Deutschland Gmbh, Aventis Pharma S.A., Abbott Gmbh, Abbott Laboratories and Abbott Laboratories, Inc. ("ALI") (collectively, "Abbott")(collectively, "Plaintiffs"), and seven motions in limine filed by Defendants Glenmark Pharmaceuticals, Inc., USA and Glenmark Pharmaceuticals, Ltd. (collectively, "Defendants") to dismiss pursuant to Fed. R. Civ. P. 12(b)(1). Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of all parties, it is the decision of this Court for the reasons herein expressed that Plaintiffs' motion in limine #1 is granted in part and denied in part, motions in limine #2 and #4 are granted, and motions in limine #3 and #5 are denied, and Defendants' motions in limine #1, #2, #3, #4,#6, and #7 are denied and motion in

limine #5 is granted.

II. RELEVANT LAW

A. Federal Rule of Evidence 402 provides: "All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible."

B. Federal Rule of Evidence 403 provides: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."

C. Federal Rule of Evidence 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

D. Federal Rule of Evidence 703 provides: "The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference

to be admitted. Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect."

E. 35 U.S.C. § 284 provides: "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court. When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title. The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances."

F. Federal Rule of Civil Procedure 26(a)(2)(B)(i) provides: "(2) Disclosure of Expert Testimony...(B) Witnesses Who Must Provide a Written Report. Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report--prepared and signed by the witness--if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them."

G. Federal Rule of Civil Procedure 37(c)(1) provides: "If a party fails to provide

information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless."

III. PLAINTIFFS' MOTIONS IN LIMINE

A. Plaintiffs' *Motion in Limine* #1 to Exclude References to Patent Monopoly and Relative Prices of Generic v. Brand Name Drugs Pursuant to Fed. R. Evid. 702 and 703 and Fed. R. Civ. P. 37(c).

Plaintiffs ask this Court to preclude Defendant from informing jury (1) that generic drugs are less expensive, (2) the purpose of Hatch-Waxman is to balance the rights of the innovator with those of generic drug manufacturers, (3) Plaintiff has a patent monopoly, and (4) the expected role of generic drugs in the healthcare reform.

Plaintiffs argue that the above arguments amount to asking the jury to nullify the patent in favor of less expensive generic drugs and that patent exclusivity is unfair, and that the benefits of generic drug pricing are irrelevant to the two issues in the case, namely obviousness and damages. Plaintiffs claim that labeling the patent as a monopoly amounts to asking the jury to nullify the patent statute and find patents are unfair. Plaintiffs claim these arguments are perjorative and misdirected based on case law from the Federal Circuit. Plaintiffs also claim that the process of approval for generic brand drugs, the Hatchman-Waxman balance between innovators and generic, and the alleged role of generic drugs in the healthcare reform are irrelevant.

Defendants make several arguments in opposition to Plaintiffs' *Motion in Limine*. First, the Defendants contend that the pricing of brand name drugs versus generic drugs is neither prejudicial nor controversial as the difference in pricing is a matter of common sense. Defendants also argue

that this information is relevant to the issue of damages as Plaintiffs' expert is expected to testify regarding sales prices of brand name versus generic drugs, price erosion and reasonable royalties. Second, Defendants argue that testimony regarding the Hatch-Waxman regulatory scheme, generic pharmaceutical industry, and the Abbreviated New Drug Application ("ANDA") process provide context and background that is necessary for the case. In support of its position, Defendants cite to a decision of this Court where this Court stated that "testimony concerning Hatch-Waxman and generic drugs likely aid jury in understanding the context." Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., 2009 WL 3754170 (D.N.J. Nov. 5, 2009). In Novartis, this Court allowed an initial and limited presentation on Hatch-Waxman, but did not allow any evidence regarding the effect of generic drugs in healthcare reform because it was totally irrelevant to any issue in the case. Third, Defendants argue that evidence that it acted in compliance with Hatch-Waxman and FDA regulations is required so that Defendants are not portrayed as wrongdoers who disregard patent rights. Fourth, Defendants argue that if Plaintiffs are allowed to present evidence regarding the development and approval of its drug, Defendants should likewise be allowed. Fifth, Defendants argue that Plaintiffs do in fact have a monopoly through which Plaintiffs exclude generic brands and "erect a hurdle" for ANDA.

Based on the parties' arguments, Plaintiffs' motion is granted in part, and denied in part. Specifically, Plaintiffs' motion with regard to precluding references to a patent monopoly or the role of generic drugs in healthcare reform is granted; Defendants are precluded from extolling the benefits of generic drug pricing, but testimony regarding the difference in prices between generic and brand name drugs is allowed since the experts have relied on such costs in their respective damages analysis; and Defendants are allowed to present an initial and limited presentation of Hatch-Waxman

and the generic approval process.

B. Plaintiffs' *Motion in Limine* #2 to Exclude Evidence and References Concerning this Court's Preliminary Injunction Opinion and Abbotts' Request for Injunctive Relief Pursuant to Fed. R. Evid. 402 and 403.

Plaintiffs argue that any finding of fact or conclusion of law made at the preliminary inunction stage is not binding in a subsequent trial. Additionally, this Court's denial of the preliminary injunction is not relevant to any issue that the jury is to decide. Plaintiffs argue that informing the jury of the denial of the preliminary injunction would significantly and unduly prejudice the Plaintiffs. Plaintiffs also argue that the fact Abbott sought a preliminary injunction is not a matter for the jury because whether injunctive relief is appropriate is a matter for the court. Finally, Plaintiffs argue that the jurors could be prejudiced if they are aware their decision at trial could prevent the sales of generic drugs.

In response, Defendants state that it is only going to refer to, and introduce evidence of, the preliminary injunction opinion and order if Plaintiffs introduce evidence, or argue, that Defendants' launch of the generic drug was improper. Based on Plaintiffs' contested facts, Plaintiffs intend to argue that Defendants' launch was at risk and characterize the launch as infringing marketing and sales. However, Defendants cannot infringe if the patent is not valid. Defendants argue it would be prejudicial to characterize Defendants as "bad actors" for launching the generic, especially because the launch occurred after Plaintiffs' motion for preliminary injunction was denied. Defendants' position is that if Plaintiffs are allowed to characterize Defendants in such a way, Defendants should be allowed to rebut by informing the jury that this Court found there were substantial questions as to the patent's validity.

Defendants also state that it is only going to present evidence on the request for the permanent injunction if Plaintiffs raise the issue. Plaintiffs' damages expert is expected to testify about the effects on lost profits of this Court granting a permanent injunction and ordering a recall of the generic drugs.

Based on the parties' arguments and this Court's determination that the denial of the preliminary injunction is irrelevant and prejudicial, Plaintiffs' motion is granted.

C. Plaintiffs' *Motion in Limine* #3 to Exclude Testimony of Defendant's Damages Expert, Ivan Hoffman, Pursuant to Fed. R. Evid. 403, 702, and 703.

Plaintiffs seek to exclude the opinion of Defendant's damages expert, Ivan Hoffman ("Hoffman"), regarding reasonable royalty on the grounds that it fails to meet the standard of Fed. R. Evid. 702 (i.e. it is not the product of reliable principles and methods) and 703 (i.e. the information is not the type reasonably relied upon by experts in the field). Plaintiffs contend that Hoffman's opinion is based on faulty and improper methodology, and is contrary to the case law of the Federal Circuit regarding reasonable royalty analysis. Reasonable royalty analysis is based on a hypothetical negotiation of a licensing agreement reached at the time infringement began. The analysis assumes that the patent is valid and infringed, and presumes both parties were operating under the assumption the patent was valid, enforceable, and infringed. The hypothetical negotiation in a reasonable royalty calculation occurs before litigation.

Plaintiffs argue that Hoffman ignores the legal authorities regarding reasonable royalty analysis, and includes the question of patent validity in his analysis thereby resulting in lower rates. Plaintiffs state the following as evidence that Hoffman's report is not based on valid reasoning and reliable methods: (1) he assumes the parties enter the negotiations with knowledge of this Court's

denial of the preliminary injunction and Defendant's ability to launch the generic without a license, (2) he opines a 10% reasonably royalty rate supported by denial of the preliminary injunction, specter of the generic launch, litigation uncertainty regarding validity, and costs of litigation, and (3) he criticizes Plaintiffs' expert for not including the question of validity in his analysis.

Since the Federal Circuit has determined that reasonable royalty analysis cannot include a question of patent validity, Plaintiffs argue that Hoffman's opinion would violate Fed. R. Evid. 702 & 703 because it is not based on valid reasoning or reliable methods. Plaintiffs also argue that since Hoffman's opinion is based on an incorrect legal standard, there is substantial risk it will confuse the jury and should be excluded under Fed. R. Evid. 403.

Defendants argue that Plaintiffs' characterization of Hoffman's expert report is false, and that the report is the product of reliable principles and methods and based on the type of information relied upon by experts in the field. Specifically, Hoffman's expert report did not assume the patent is invalid. On its face, the opinion says it assumes the patent is valid. Also, the deposition testimony of the parties' experts show there is no factual basis for Plaintiffs' allegation. Defendants argue that there are two parts to Hoffman's reasonable royalty analysis: (1) it applies the traditional *Georgia-Pacific* factors to determine a reasonable royalty rate,[1] and (2) it critiques Plaintiffs' expert's reasonable royalty analysis based on "game theory." Hoffman's critique originally included the risk of invalidity of the patent because it was not clear that Plaintiffs' expert's game theory analysis was dependent on the *Georgia-Pacific* factors; now that he understands Plaintiffs' expert correctly, Hoffman will not rely on the risk of invalidity in his critique.

[1]The report includes 34 pages of analysis of the *Georgia-Pacific* factors and assumes the patent is valid and infringed.

Defendants also assert that Hoffman did not rely on the preliminary injunction in coming up with a reasonable royalty rate, but rather the preliminary injunction decision supports the conclusion at which he independently arrived. Furthermore, Hoffman made clear in his deposition that he would not testify regarding the denial of the preliminary injunction in relation to his reasonable royalty analysis.

In sum, Defendants argue that Hoffman did not ignore legal authority, correctly assumed the patent's validity, and based his expert opinion on valid methods and reasoning, and therefore should not be precluded from testifying.

Based on the parties' arguments, Plaintiffs' motion is denied.

D. Plaintiffs' *Motion in Limine* #4 to Exclude Evidence and Testimony Under the Collateral Source Rule and Pursuant to Fed. R. Evid. 402 and 403.

Plaintiffs seek to exclude evidence and testimony relating to payment between co-Plaintiffs Sanofi Aventis ("Aventis") and Abbott as inadmissible under the collateral source rule and as irrelevant and unduly prejudicial.

Under the 2004 Licensing Agreement ("Agreement") for manufacturing rights to the patent, Abbott paid $290 million in up front payments to Aventis. Of that amount, approximately $150 was credited to exclusive license to the patent-in-suit. The Agreement provided for a price reduction from the up front payments based on the date a generic product enters the market place. The price reduction for 2010 is $50 million, which is to be paid from Aventis back to Abbott.

According to Plaintiffs, Defendants intend to introduce evidence regarding the price reduction and improperly argue that the payment should act as compensation, or to offset the damages from infringing. Plaintiffs argue that this is wrong as a matter of law and highly prejudicial,

and therefore should be excluded.

Plaintiffs argue that patent infringement is a tort, and under the collateral source rule a tortfeasor cannot benefit from payment to the injured party from a third party; the fact that the plaintiff received pecuniary advantage from a collateral source cannot be used to mitigate damages. In other words, the tortfeasor cannot benefit from rights the victim has against another through contract or benefit from payments made to the victim by a collateral source. Additionally, Plaintiffs argue that there is no form of patent damages that allows Defendant to mitigate liability with collateral source payments because the damages are tied directly to infringers actions and liabilities. See e.g. 35 U.S.C. § 284 ("in no event less than reasonable royalty for the *use made by the infringer*.")(emphasis added). Plaintiffs argue that lost profits are tied to lost sales and other financial considerations, such as fixed costs, are irrelevant. Plaintiffs further argue that presenting the jury with even an implicit suggestion that the price reduction payment can, or should, offset the damages is unfairly prejudicial.

Defendants argue that the payment is a direct result of the infringement and makes Abbott whole, and therefore is relevant. Defendants focus on the part of 35 U.S.C. § 284 that states "award damages adequate to compensate for the infringement but in no event less than a reasonable royalty." Defendants agree that, if the patent is found valid, Plaintiffs are owed a reasonable royalty, but Defendants argue that if it pays Plaintiffs lost profits the result would be over compensation of the Plaintiffs. Defendants argue that the purpose of the statute is to compensate adequately for infringement and to make the patentee whole. As Defendants frame it, the issue is whether a patentee (or here, licensee) who is fully compensated for actual economic detriment can recover again; if the patentee has not actually been economically harmed, than he cannot recover.

Accordingly, Defendants claim that the payment is relevant because the jury needs to know the relevant economic position of Plaintiffs pre- and post-infringement.

Defendants also state that even if this Court finds that the payment from Aventis cannot actually offset the damages, the jury should know of the payment. Defendants claim that evidence of the payment would not be used to improperly persuade the jury but to show the relative economic position of the Plaintiffs pre- and post-infringement. However, the only apparent value in informing the jury would be to inform their decision regarding damages, and thereby have the payment offset the damage through the back door.

Based on the parties' submissions, Plaintiffs' motion is granted.

E. Plaintiffs' *Motion in Limine* #5 to Exclude Any Chemistry and/or Animal Pharmacology Testimony of Defendant's Expert, Dr. Clive Rosendorff, and *Daubert* Motion to Preclude from Testifying Outside his Expertise Pursuant to Fed. R. Evid. 702 and Fed. R. Civ. P. 26(a)(2)(B)(I) and 37(c)(1).

Plaintiffs move to preclude Defendants' expert, Clive Rosendorff ("Rosendorff"), from testifying outside of his expertise in cardiovascular medicine; specifically Plaintiffs move to preclude testimony relating to chemistry, chemical structures and animal pharmacology based on Fed. R. Evid. 702. Plaintiffs also move to exclude testimony relating to chemistry and chemical structures based on Fed. R. Civ. P. 26(a)(2)(B)(i) and 37(c)(1).

Plaintiffs challenge Rosendorff's qualifications relating to chemistry and animal pharmacology, and claim that Rosendorff is an M.D., but not a chemist or pharmacologist and is without work experience in either field. Although recognizing that the level of ordinary skill is a question for the jury to decide, Plaintiffs still seem to be asking this Court to reject Rosendorff as

an expert based on Plaintiffs' definition of a person of ordinary skill in the art. Plaintiffs' definition of a person of ordinary skill in the art is a collaboration of scientists having background in medicinal or organic chemistry, pharmacology, and cardiovascular medicine. Plaintiffs rely on Rosendorff's deposition to show he is not a chemist or pharmacologist, and argue that Rosendorff is therefore not a person of ordinary skill in the art (based on Plaintiffs' definition) and should not be allowed to testify. Plaintiffs argue that chemistry and pharmacology expertise are relevant to understanding obviousness, prior art, and the invention. Plaintiffs argue that training in cardiology and medicine and a background in clinical trials is not enough to qualify as an expert; a medical degree is not sufficient to permit expert testimony regarding any medical related issue, and the expert must be confined to his area of specialty. Here, Plaintiffs' argue that Rosendorff's area of specialty is cardiology of high blood pressure and hypertension drugs.

Plaintiffs' also argue that Rosendorff's opinion testimony relating chemistry and chemical structure should be excluded under Fed. R. Civ. P. 26(a)(2)(B)(i)and 37(c)(1). Plaintiffs claim that, except for verbatim recitation of the claims of the patent-in-suit and of its grandparent patent, Rosendorff's expert report fails to mention or discuss chemical structure, chemistry, whether ACE inhibitors have single or double ring structures or other chemical issues. Additionally, Plaintiffs argue that Rosendorff was unwilling during his deposition to provide examples of testimony he would be giving regarding the chemistry of the drugs at issue.[2] Therefore, Plaintiffs argue that Rosendorff's testimony on the issue of chemistry should be excluded under 37(c)(1) for failure to provide a complete statement of all opinions he will express, and the basis and reasons for them in

[2]Based on the information provided, it appears that Dr. Rosendorff's responses at his deposition basically amounted to saying he would answer any questions regarding chemistry to the best of his ability.

compliance with Fed. R. Civ. P. 26(a)(2)(B)(i).

In response, Defendants first argue that the motion should be denied strictly based on the Pre-Trial Order. In the Pre-Trial Order, the parties agreed that they would not challenge the qualifications of respective experts.

Defendants also argue that Rosendorff is qualified as an expert witness in chemistry and pharmacology. Defendants point out that Rosendorff has published more than 50 original research papers in peer reviewed journals and 7 book chapters in the field of animal models and animal pharmacology, as well as 42 original peer reviewed papers and 11 book chapters in the area of human pharmacology. Defendants also note that Rosendorff had to read and understand various studies in these fields as part of his research. Rosendorff has also consulted with numerous companies regarding cardiovascular pharmacology, including Abbott. Also, although he is not a chemist, Rosendorff is a trained and experienced researcher who has extensively studied drug mechanism and action of anti-hypertensive drugs, including the class of drugs at issue, and published several papers on the subject.

Additionally, Defendants argue that Rosendorff would qualify as an expert under Defendants' definition of a person of ordinary skill in the art, which is a medical scientist, such as a pharmacologist or medical doctor involved in pharmacological research; such a person would have a M.D. or Ph.D. in pharmacology or a related field, and several years experience in research in the treatment of cardiovascular disease.

Defendants also argue that Plaintiffs are contradicting their own as one of Plaintiffs' experts also only has an M.D. and is an expert in cardiology, but has opined on all prior art references discussing animal pharmacology. Additionally, one of Plaintiffs' experts relies in his rebuttal expert

report on a paper published by Rosendorff.

With regard to Plaintiffs' arguments under 26(a)(2)(B)(i) and 37(c)(1), Defendants argue that Rosendorff's expert report contains descriptions of structures disclosed in the patent, several prior art publications disclosing molecular structures, and opinions on the prosecution history. Additionally, Defendants argue that Rosendorff was deposed on the chemistry related issues in his report, namely the structures disclosed in the claim and why he believes they are obvious.

Based on the parties' submissions, and this Court's finding that the issues raised go to the weight, not admissibility, of Rosendorff's testimony and that Rosendorff's expert report complied Fed. R. Civ. P. 26(a)(2)(B)(i) and 37(c)(1), Plaintiffs' motion is denied.

IV. DEFENDANTS' MOTIONS IN LIMINE

A. Defendants' *Motion in Limine* #1 to Preclude Evidence of Alleged Unexpected Results.

Defendants move to preclude Plaintiffs from showing unexpected or superior properties of the subject matter of Claim 3 of the patent (the only claim in issue). Specifically, Defendants are moving to preclude Plaintiffs from relying on evidence or testimony comparing the claimed composition to prior art compositions or other drugs that are not the closest prior art.

TARKA, the drug at issue, is composed of two active ingredients: an ACE inhibitor trandolapril and a calcium antagonist verapamil. Claim 3 of the patent covers the pharmaceutical composition comprising of an ACE inhibitor (either trandolapril or quinapril) and calcium antagonist.

In response to Defendants' argument that the patent is invalid because it was obvious to those of ordinary skill in the art at the time of the patent, Plaintiffs are expected to present evidence of

secondary or objective indicia of non-obviousness, including unexpected or surprising results. In order to show the unexpected or surprising results, Plaintiffs are expected to rely on comparisons between compositions in Claim 3 and other antihypertensive drug products. The parties agree that the closest prior art is an enalapril and calcium antagonist combination (the "Garthoff composition"). Plaintiffs will rely on nine comparisons, but none are a head-to-head comparison of the claimed composition and the Garthoff composition. Defendants claim that in order to rely on comparisons to establish unexpected results, the patentee must show the claimed composition is superior to the closest prior art. Since the comparisons on which Plaintiffs are expected to rely are not to the closest prior art, Defendants argue they are irrelevant and should be excluded.

In response, Plaintiffs state that they intend to offer comparisons between the claimed trandolapril-calcium antagonist composition, or the quinapril-calcium antagonist composition, and the prior art identified and relied upon by the Defendants in their challenge to the patent's validity. Plaintiffs argue that these comparisons are relevant to the factual analysis regarding the differences between the prior art and the claim at issue.

Plaintiffs argue that Defendants' position that only comparisons to the Garthoff composition may be used to show differences and indirect comparisons (i.e. comparisons to the other compositions referenced by Defendant) cannot be used to show differences is unsupported by case law. First, Plaintiffs argue that differences between the claimed invention and prior art are always relevant, both for unexpected results and for the prima facie case of obviousness the Defendants must prove. For example, Plaintiffs argue the comparisons they are relying on will show three secondary considerations that prove non-obviousness, namely the long felt need for a combination drug that would be taken once a day, the benefits of the claimed combination, and the recognition

of the value of the claimed combination in the scientific community. Second, with regard to unexpected results, the "closest prior art" does not mean only the single, closest reference, but rather refers to the all the prior art used by the Patent Office or by a challenger in a suit challenging the patent's validity. Here, Defendants rely on twelve references, including hypertensive monotherapy (i.e. trandolapril or quinapril alone), to show the obviousness of the patent. Therefore, Plaintiffs' comparisons to those same references is relevant to rebut the Defendants' argument. Third, there is no rule that requires comparisons to be made head-to-head; Plaintiffs can show unexpected results, and other differences, by comparing positive results for combination in one article with negative results for different combinations described in prior art in a separate article.

Based on the parties' arguments, Defendants' motion is denied.

B. Defendants' *Motion in Limine* #2 to Preclude Plaintiffs from Referring to Defendants' Stipulation of Infringing During the Invalidity Phase.

Defendants' motion was predicated on the grant of its Motion to Stage the Trial to Determine Liability Prior to Presentation of Damages. Defendants' Motion to Stage the Trial was denied. Therefore, this motion is denied.

C. Defendants' *Motion in Limine* #3 to Preclude Plaintiffs from Characterizing Defendants' ANDA Product as a "Copy" of the TARKA Product.

Defendants seek to preclude Plaintiffs from characterizing Defendants' ANDA product as a "copy" or "copycat" TARKA product "or the like" on the grounds that it is misleading, unfairly prejudicial and irrelevant. Defendants argue that its product is the bioequivalent of TARKA because the generic drug is required by the FDA to contain the same active ingredients in the same amount as TARKA, and the generic must meet certain physiological requirements. The generic drug was

produced through independent research and development, and is not a copy or copycat of TARKA. Defendants claim that to argue that the generic is a copy or copycat is unfairly prejudicial because it unfairly characterizes Defendants as dishonest or disreputable. Generic drugs are legally encouraged under Hatch-Waxman and Defendants complied with the law, so Defendants argue it should not be unfairly characterized as a bad actor. Also, since the only issue with regard to validity is obviousness whether or not the generic is a copy is irrelevant.

Plaintiffs point out that Defendants cite no case law supporting its argument, and would not be able to cite any support because copying is relevant as a recognized secondary consideration of non-obviousness. Copying, as secondary considerations evincing non-obviousness, is important part of demonstrating non-obviousness even in a pharmaceutical patent case against an ANDA filer because an ANDA filer is not *required* to copy. In support of its argument, Plaintiffs cite to a decision of this Court which found evidence of copying relevant to the obviousness determination. Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., 2009 WL 3754170 (D.N.J. Nov. 5, 2009). Plaintiffs argue that the fact that Defendants chose to copy, as opposed to using a bioequivalent, hurts its obviousness case, but is not unfairly prejudicial. Plaintiffs further argue that to prevent Plaintiffs from characterizing the generic drug as a copy would prevent Plaintiffs from showing the secondary considerations of copying are met.

Based on the parties' arguments, Defendants' motion is denied.

D. Defendants' *Motion in Limine* #4 to Preclude Plaintiffs from Arguing that Any Party Other than Abbott Laboratories Inc. is entitled to Lost Profits.

Defendants seek to preclude Plaintiffs from arguing that any party other than ALI is entitled to lost profits damages. Defendants argue that the Abbott Entities' corporate structure is one of

separate economic entities making separate contributions to the TARKA supply chain, with each entity is assigned a specific transfer price for TARKA. However, Defendants argue that ALI is the only Abbott entity that makes, uses, or sells TARKA in the United States. Therefore, Defendants argue, Plaintiffs should not be allowed to argue for lost profits based on the lost profits of the consolidated Abbott Entities, but rather should only be entitled to argue for ALI's lost profits.

In support of their argument, Defendants rely on Poly-America, L.P. v. GSE Lining Tech., Inc., 383 F.3d 1303 (Fed. Cir. 2004). In Poly-America, Poly-America was the owner of the patent and its sister corporation was a non-exclusive licensee. Id. at 1311. The Federal Circuit reversed the district court's award of lost profits to Poly-America based on its sister corporation's lost profits. Id. at 1310. The Federal Circuit rejected the argument that Poly-America and its sister corporation operated as a single economic unit, and found that the two corporations were separate corporate entities. Id. The Federal Circuit found that Poly-America and its sister corporation "may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure - in this case, the inability of the patent holder to claim the lost profits of its *non-exclusive licensee*." Id. at 1311 (emphasis added).

Plaintiffs argue that since each Plaintiff is either the patent owner or an exclusive licensee, each Plaintiff should be allowed to argue for lost profits. Plaintiffs note that under the broadly worded patent statute, patent owners and exclusive licensees are entitled to "damages adequate to compensate for infringement." 35 U.S.C. § 284. Therefore, Plaintiffs argue that a patent owner or exclusive licensee is entitled to recover the lost profits it suffered as result of infringement, regardless of whether it made, used, or sold the patented device. Plaintiffs also argue that when profits flow up to a corporate parent, the parent can recover the profits it normally would have

enjoyed but for the infringement. Additionally, Plaintiffs argue that there is no prohibition on multiple plaintiffs recovering damages. Specifically, Plaintiffs challenge Defendants reliance on Poly-America, and argue that Poly-America is distinguishable from the instant case. Here, a parent corporation, as a co-plaintiff to the litigation and exclusive licensee to the patent, is seeking lost profits it would normally enjoy but for the infringement, whereas in Poly-America a sister corporation, which was a third party to the litigation, was trying to recover lost profits even though it "lack[ed] any exclusive rights" to the patent and "hence [was] not entitled to damages for infringement." 383 F.3d at 1310.

Based on the parties' arguments, this Court's prior determination that each Plaintiff is either a patent owner or an exclusive licensee, and this Court's determination that the instant case is factually distinct from that of Poly-America, Defendants' motion is denied.

E. Defendants' *Motion in Limine* #5 to Preclude Plaintiffs from Presenting Post Judgment Damages Calculations at Trial Pursuant to Fed. R. Evid. 403.

Defendants move to preclude Plaintiffs from presenting post judgment damages calculations on the grounds that a ruling in this case is expected by February 2011, damages asserted beyond February 2011 are inappropriate and speculative, and therefore properly excluded under Fed. R. Evid. 403.

Plaintiffs seek damages from the lost sales of TARKA, and Plaintiffs' expert's report presents various calculations extending past February 2011. Specifically, Plaintiffs' expert opines Plaintiffs suffered lost profits including price erosion as a result of the generic launch and presents damages through February 2012, and Plaintiffs' expert opines on a reasonable royalty rate and presents damages through February 2015.

Defendants argue that if the patent is found invalid, this Court will grant an injunction preventing the continuing sales of the generic drug or grant an ongoing royalty. The fact that this Court can grant injunctive relief makes presentation of damages past February 2011 inappropriate. Additionally, Plaintiffs' expert has admitted the damage calculations beyond February 2011 are speculative and based on "what-if" scenarios. Plaintiffs' expert's opinion that Plaintiffs are owed millions of dollars based on post February 2011 sales will mislead and confuse the jury, and may result in excessive damages. Furthermore, post trial damages are based on different factors and economic considerations than pre-judgment damages, and are a matter for the court, not the jury.

In response, Plaintiffs state that they will not present post judgment damage calculations at trial, and will instead seek an accounting if the patent's validity is affirmed. However, Plaintiffs then go on to state that they will present evidence regarding the continuing and irreparable harm caused by sales because those are factors in granting an injunction; Plaintiffs state that presenting evidence of continuing and irreparable harm will ensure Plaintiffs are not later prejudiced if this Court does not hold an injunction hearing. Plaintiffs also state that continuing and irreparable harm, including lost sales and price erosion, are relevant to the reasonable royalty analysis because that information would be necessary in a hypothetical negotiation.

Based on the parties' arguments, Defendants' motion is granted.

F. Defendants' *Motion in Limine* #6 to Preclude Plaintiffs from Arguing that Any License for the Patent-in-Suit is Evidence of Non-Obviousness.

Defendants move to preclude Plaintiffs from arguing that their license for manufacturing rights to the patent is evidence of non-obviousness. Generally license of a patent may be evidence of non-obviousness because the licensee presumably would not pay for the license unless convinced

of the patent's validity. However, Defendants argue that in Hatch-Waxman cases the NDA holder has a separate motivation to purchase a license that is unconnected to the validity of the patent, namely the ability to prevent others from entering the marketplace for 30 months. According to Defendants, the incentive to license a patent, whether or not it is valid, is to list it in the Orange Book and thereby acquire the ability to prevent a generic competitor from entering the market for 30 months. Defendants conclude that the value of the license is actually the 30 month stay, not the validity of the patent, and argue that Plaintiffs should therefore be precluded from arguing the license is indicative of non-obviousness.

Plaintiffs intend to present evidence at trial that Abbott Germany licensed the patent from Aventis for $150 million dollars, and that the $150 million is secondary indicia of non-obviousness because Abbott Germany would not have paid that amount if the patent were not valid. Licensing agreement is relevant because it is a secondary consideration of non-obviousness, and "secondary considerations of non-obviousness must be considered when present." Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC, 618 F.3d 1294, (Fed. Cir. 2010).

Plaintiffs argue that Defendants have pointed to no fact supporting its theory that the value of the license was solely the 30 month stay, and further argue that facts support Plaintiffs' claim that the value of the license was related to the manufacturing rights.

Based on the parties' arguments, Defendants' motion is denied.

G. Defendants' *Motion in Limine* #7 to Preclude the Reasonable Royalty Opinions of Plaintiffs' Damages Expert Dr. Mohan Rao.

Defendants move to preclude Plaintiffs from offering the reasonable royalty testimony of their damages expert Dr. Mohan Rao ("Rao"). Defendants rely on the Federal Circuit decision in

Uniloc USA, Inc. v. Microsoft Corp., 2010-1035, -1055 (Fed. Cir. Jan. 4, 2011), in support of their motion.

In Uniloc, the damages expert based his reasonable royalty rate on a 25 percent rule of thumb[3] as a starting point and then applied the Georgia-Pacific factors. Uniloc, 2010-1035, -1055 at 34. The Federal Circuit identified three problems with the 25 percent rule: 1) "it fails to account for the unique relationship between the patent and the accused product," 2) "it fails to account for the unique relationship between the parties," and 3) "the rule is essentially arbitrary and does not fit within the model of the hypothetical negotiation within which it is based." Id. at 38-39. Accordingly, the Federal Circuit rejected the use of the 25 percent rule of thumb as a "fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation," and found evidence based on the application of the 25 percent rule of thumb "inadmissible under Daubert and the Federal Rules of Evidence, because it fails to tie a reasonable royalty base to the facts of the case at issue." Id. at 41.

Defendants argue that Rao's approach is indistinguishable from the approach rejected by the Federal Circuit in Uniloc in that Rao essentially applied a 50 percent rule of thumb in determining the reasonable royalty rate. Specifically, Defendants argue that Rao mechanically applied a 50/50 profit split between Abbott and Glenmark, and that Rao routinely uses a 50/50 split regardless of the patent, technology, industry or parties involved. Defendants also argue that Rao's merely pays "lip service" to the Georgia-Pacific factors, and that reference to these factors is irrelevant since Rao starts and ends with the 50/50 split.

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[3]"The 25 percent rule of thumb is a tool that has been used to approximate the reasonable royalty rate that the manufacturer of a patented product would be willing to offer to pay to the patentee during a hypothetical negotiation." Uniloc, 2010-1035, -1055 at 36.

Plaintiffs argue that game theory, which is what Rao used in determining his reasonable royalty rate, is the standard model in economics for calculating the outcome of a negotiation, is recognized as a scientific method in determining reasonable royalty rates, and is unrelated to the 25 percent rule rejected in Uniloc. Plaintiffs argue that Rao's analysis does not suffer from the three flaws identified in Uniloc, but rather uses these factors to determine the reasonable royalty rate. Plaintiffs argue that Rao did not arbitrarily apply a 50/50 profit split, but rather reached that result after considering the facts of the case, specifically the relationship between the parties and their relative bargaining power, the relationship between the patent and the accused product, the standard profit margins in the industry, and the presumed validity of the patent.

Based on the parties' arguments and this Court's determination that Rao did not arbitrarily apply a 50/50 profit split akin to the 25 percent rule rejected in Uniloc but rather based his reasonable royalty analysis on the specific facts of this case, Defendants' motion is denied.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Dated: February 3, 2011
cc: All Counsel of Record
Hon. J. A. Dickson, U.S.M.J.
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